APPENDIX B

The pending claims, as currently amended, are as follows:

1. An injectable composition suitable for tissue bulking in a mammal which comprises biocompatible, swellable, hydrophilic, non-toxic and substantially spherical microspheres and a biocompatible carrier, wherein said composition is injectable through needles of about 18 to 26 gauge and wherein said microspheres swell to a predetermined size after injection within the non-dermal tissue of said mammal.

2. The composition of claim 1, wherein the composition comprises the microspheres in an amount from about 10% to about 90% by weight and the biocompatible carrier in an amount from about 10% to about 90% by weight.

3. The composition of claim 2, wherein the composition comprises the microspheres in an amount from about 10% to about 50% by weight and the biocompatible carrier in an amount from about 50% to about 90% by weight.

4. The composition of claim 1, wherein the composition is a suspension of said microspheres in said biocompatible carrier.

5. The composition of claim 4, wherein the biocompatible carrier is an emulsion.

6. The composition of claim 4, wherein the biocompatible carrier is an organic or non-aqueous solution.

7. The composition of claim 4, wherein the biocompatible carrier is an aqueous based solution, a hydro-organic solution, or mixtures thereof.

8. The composition of claim 4, wherein the biocompatible carrier comprises salts composed of cations selected from the group consisting of sodium, potassium, calcium, magnesium, iron, zinc, and ammonium in an amount of from about 0.01 M to about 5 M.

9. The composition of claim 8, wherein the salt is supplied in form of a contrast agent.

10. The composition of claim 4, wherein the biocompatible carrier is acylamino-e-propion-amido-3-triiodo-2, 4, 6-benzoic acid.

11. The composition of claim 1, wherein average diameters of the microspheres after injection are about 1 to 4 times of average diameters of the microspheres immediately prior to injection.

12. The composition of claim 1, wherein the microspheres comprise sodium acrylate polymer, acrylamide polymer, acrylamide derivative polymer or copolymer, sodium acrylate and vinyl alcohol copolymer, vinyl acetate and acrylic acid ester copolymer, vinyl acetate and methyl maleate copolymer, isobutylene-maleic anhydride crosslinked copolymer, starch-acrylonitrile graft copolymer, crosslinked sodium polyacrylate polymer, crosslinked polyethylene oxide, or mixtures thereof.

13. The composition of claim 12, wherein the polymers comprise from about 0.5% to about 20%, by molecular weight, of crosslinkers.

14. The composition of claim 1, which further comprises cells associated with surfaces of at least a portion of the microspheres prior to injection.

15. The composition of claim 14, wherein the cells are autologous cells from the subject mammal.

16. The composition of claim 15, wherein the autologous cells are fat cells, muscle cells, subcutaneous cells, dermal cells, epidermal cells, or combinations thereof.

17. The composition of claim 1, further comprises therapeutic agent, radio-pacifying agent, contrast medium, or mixtures thereof.

18. The composition of claim 17, wherein said agents or medium are bound to the microspheres.

19. The composition of claim 17, wherein the therapeutic agent is anti-inflammatory agent.

20. The composition of claim 1, wherein the microspheres are capable of being chemically modified to have therapeutic effects, anti-inflammatory effects, anti-bacterial effects, anti-histamine effects, or combinations thereof.

21. A method of tissue bulking in a mammal comprising injecting a composition comprising biocompatible, swellable, hydrophilic, non-toxic and substantially spherical microspheres in a biocompatible carrier into the non-dermal tissue of said mammal through a needle of about 18 to 26 gauge.

22. The method of claim 21, wherein the composition is a suspension of said microspheres in said biocompatible carrier.

23. The method of claim 21, wherein the microspheres swell upon contacting with physiological fluids at injection site.

24. The method of claim 23, wherein diameters of the microspheres after injection are about 1 to about 4 times of diameters of the microspheres immediately prior to injection.

25. The method of claim 21, wherein the microspheres comprise sodium acrylate polymer, acrylamide polymer, acrylamide derivative polymer or copolymer, sodium acrylate and vinyl alcohol copolymer, vinyl acetate and acrylic acid ester copolymer, vinyl acetate and methyl maleate copolymer, isobutylene-maleic anhydride crosslinked copolymer, starch-acrylonitrile graft copolymer, crosslinked sodium polyacrylate polymer, crosslinked polyethylene oxide, or mixtures thereof.

26. The method of claim 25, wherein the polymers comprise from about 0.5% to about 20%, by molecular weight, of crosslinkers.

27. The method of claim 21, which further comprises cells associated with surfaces of at least a portion of the microspheres prior to administration.

28. The method of claim 27, wherein the cells are autologous cells from the subject mammal.

29. The method of claim 28, wherein the autologous cells are fat cells, muscle cells, subcutaneous cells, dermal cells, epidermal cells, or combinations thereof.

30. The method of claim 22, wherein the biocompatible carrier is an emulsion.

31. The method of claim 22, wherein the biocompatible carrier is organic or non-aqueous solvent.

32. The method of claim 22, wherein the biocompatible carrier is an aqueous solution, a hydro-organic solution, or mixtures thereof.

33. The method of claim 22, wherein the biocompatible carrier comprises salts composed of cations selected from the group consisting of sodium, potassium, calcium, magnesium, iron, zinc, and ammonium in an amount of from about 0.01 M to about 5 M.

34. The method of claim 33, wherein the salt is supplied in form of a contrast agent.

35. The method of claim 22, wherein biocompatible solvent is acylamino-e-propion-amido-3-triiodo-2, 4, 6-benzoic acid.

36. The method of claim 21, wherein the composition further comprises therapeutic agent, radio-pacifying agent, contrast media, or mixtures thereof.

37. The method of claim 36, wherein said therapeutic agents are bound to the microspheres.

38. The method of claim 21, wherein the injection is into an area of said mammal in need of tissue bulking.

39. The method of claim 38, wherein the injection is into the vocal cord.

40. The method of claim 21, wherein the tissue bulking is for the treatment of Gastro-esophageal reflux disease.

41. The method of claim 40, wherein the administration comprises injecting said composition into the lower esophageal sphincter or the diaphragm of said mammal.

42. The method of claim 21, wherein the tissue bulking is for the treatment of urinary incontinence or urinary reflux disease.

43. The method of claim 42, wherein the administration comprises injecting said composition into the bladder sphincter or urethra of said mammal.

44. The method of claim 42, wherein the urinary incontinence is caused by bladder-neck hypermotility.

45. The method of claim 21, wherein the mammal is human.

46. The method of claim 21, wherein the administration comprises injecting said composition extracorporeally into organs, components of organs, or tissues prior to their inclusion into said mammal's body, organs, or components of organs.

47. A kit for performing tissue bulking comprising:
(a) an 18 to 26 gauge needle;
(b) means for injecting a liquid based composition through said needle; and
(c) biocompatible, swellable, crosslinked, hydrophilic, non-toxic and substantially spherical microspheres injectable into the non-dermal tissue of a mammal through said needle and are not capable of being digested or eliminated by macrophage or other elements of said mammal's immune system after injection thereof.

48. The kit of claim 47, wherein the means for injection is a syringe corresponding to said needle.

49. The kit of claim 47, further comprising a liquid based biocompatible carrier injectable through said needle.

50. The kit of claim 49, wherein the microspheres are suspended in the biocompatible carrier.

51. The kit of claim 50, wherein the microspheres are associated with cells.